W&H	510(k) Contra-Angle Handpiece "KOMET - OS30"	Section 5 Page 1 of 1

K090548

JUN 30 2009

510(k) SUMMARY

Applicant and Owner	W&H Dentalwerk Buermoos GmbH Ignaz-Glaser-Strasse 53 A - 5111 Buermoos - Austria Tel.: 0043 -6274 / 6236 -297 Fax: 0043 -6274 / 6236 -234
Contact Person	Johann Georg SCHARL
Date of Preparation	February 24th, 2009
Device Name	Contra-Angle Handpiece "KOMET - OS30"
Classification Name	Handpiece, Air-Powered, Dental
Regulation Number	21 CFR872.4200
Product Code	EFB
Predicate Devices	Dentsply International: "Interproximal Reduction System", K053368 A-dec Incorporated: "A-dec/W&H Synea Profin Reciprocating Contra-Angle Handpiece Attachment WA-67...", K082827
Device Description	The dental handpiece attachment "KOMET - OS30" is a drive, in order to enable the mechanical interproximal enamel reduction by means of the oscillating movement of the attached "KOMET - OS Discs". "OS30" is provided with a coupling system according to ISO 3964, allowing the handpiece's attachment onto a corresponding dental motor. The handpiece's gearing elements transmit the motor's rotational movement up to the integrated head gear, where this movement is converted into an oscillating one. The "OS Disc", chucked in the said head gear, oscillates in an angle of 30°, depending on the motor's speed with max. 5.000 oscillations/min.
Intended Use:	The dental contra-angle handpiece "KOMET - OS30" is intended for mechanical interproximal enamel reduction (stripping, slenderizing) in use of an oscillating movement.
Technological Characteristics	The handpiece "KOMET - OS30" represents a further variant of W&H's dental contra-angle handpieces series Synea, which already have been cleared by A-dec Inc. under the 510(k) numbers K993526, K070663 and just recently K053368. While the main technical characteristics have been retained unchanged, the new product's transmission elements prompt the chucked tool to move in an oscillating manner.
Comparison of the device to the predicate device	The intended use, technological characteristics and performance parameter are very similar to the predicate device cleared by Dentsply International. The technological characteristics and the materials furthermore are very similar to ones of the products cleared by A-dec Inc. The new device is substantially equivalent to the predicate devices.
Performance Testing	Bench testing results demonstrate substantially equivalence
Clinical Testing	Clinical data were not needed for this new product.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 30 2009

Mr. Johann Georg Scharl
Regulatory Affairs Manager
W& H Dentalwerk Buermoos GmbH
Ignaz-Glaser-Strasse 53
Buermoss Salzburg A-5111
AUSTRIA

Re: K090548
Trade/Device Name: Contra-Angle Handpiece "KOMET-OS30"
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EFB
Dated: June 23, 2009
Received: June 25, 2009

Dear Mr. Scharl:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Susan Runner, D.D.S., M.A.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

Device Name:

Contra-Angle Handpiece "KOMET - OS30"

Indication for Use:

The dental contra-angle handpiece "KOMET - OS30" is intended for mechanical interproximal enamel reduction (stripping, slenderizing) in use of an oscillating movement

Prescription Use _____X_____ (Part 21 CFR 801 Subpart D) AND/OR Over The Counter Use _____ (Part 21 CFR 807 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kevin Mosley for MSR

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K090548